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(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US];
One SciMed Place, Maple Grove, MN 55311 (US).

(72) Inventors: SHAPIRO, Gary; 134 Granite Street, Med-
field, MA 02052 (US). BLOSSOM, David; 5 Mayo Road,
Wellesley, MA 02481 (US). OSTROVSKY, Isaac; 5 Wil-
low Street, Wellesley, MA 02481 (US).

(74) Agents: SEAGER, Glenn, M. et al.; Crompton, Seager
& Tufte, LLC, 331 Second Avenue South, Suite 895, Min-
neapolis, MN 55401 (US).

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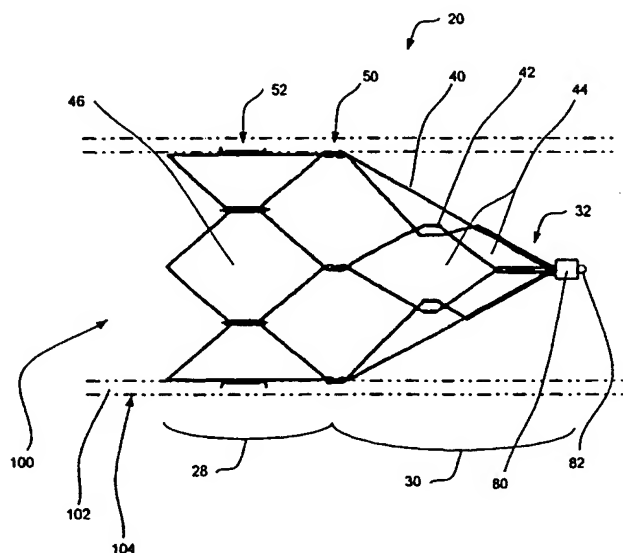
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(54) Title: INTRAVASCULAR FILTERING DEVICES AND METHODS



(57) Abstract: A thrombus filter configured for placement within a blood vessel lumen defined by a blood vessel wall. Methods and devices for selectively reshaping the thrombus filter so that the lumen of the blood vessel is substantially unobstructed. The thrombus filter includes a generally cylindrical anchoring portion, and a generally conical filtering portion terminating at an apex.

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INTRAVASCULAR FILTERING DEVICES AND METHODS

Field of the Invention

The present invention relates generally to filters for use inside blood vessels. More particularly, the present invention relates to thrombus filters which may be
5 securely affixed at a selected location in the vascular system.

Background of the Invention

There are a number of situations in the practice of medicine when it becomes desirable for a physician to place a filter in the vascular system of a patient. One of
10 the most common applications for vascular filters is the treatment of Deep Venous Thrombosis (DVT). Deep Venous Thrombosis patients experience clotting of blood in the large veins of the lower portions of the body. These patients are constantly at risk of a clot breaking free and traveling via the inferior vena cava to the heart and lungs. This process is known as pulmonary embolization. Pulmonary embolization
15 can frequently be fatal, for example when a large blood clot interferes with the life-sustaining pumping action of the heart. If a blood clot passes through the heart it will be pumped into the lungs and may cause a blockage in the pulmonary arteries. A blockage of this type in the lungs will interfere with the oxygenation of the blood causing shock or death.

20 Pulmonary embolization may be successfully prevented by the appropriate placement of a thrombus filter in the vascular system of a patient's body. Placement of the filter may be accomplished by performing a laparotomy with the patient under

general anesthesia. However, intravenous insertion is often the preferred method of placing a thrombus filter in a patient's vascular system.

Intravenous insertion of a thrombus filter is less invasive and it requires only a local anesthetic. In this procedure, the thrombus filter is collapsed within a delivery catheter. The delivery catheter is introduced into the patients vascular system at a point which is convenient to the physician. The delivery catheter is then fed further into the vascular system until it reaches a desirable location for filter placement. The thrombus filter is then released into the blood vessel from the delivery catheter.

In the treatment of Deep Venous Thrombosis, a thrombus filter is placed in the inferior vena cava of a patient. The inferior vena cava is a large vessel which returns blood to the heart from the lower part of the body. The inferior vena cava may be accessed through the patient's femoral vein.

Thrombus filters may be placed in other locations when treating other conditions. For example, if blood clots are expected to approach the heart and lungs from the upper portion of the body, a thrombus filter may be positioned in the superior vena cava. The superior vena cava is a large vessel which returns blood to the heart from the upper part of the body. The superior vena cava may be accessed through the jugular vein, located in the patient's neck.

Once placed inside a blood vessel, a thrombus filter acts to catch and hold blood clots. The flow of blood around the captured clots allows the body's lysing process to dissolve the clots.

If a filter becomes loose while positioned in the lumen of a blood vessel, it may migrate to a position where it may be ineffective at capturing thrombi.

Alternately, and more seriously, a loose thrombus filter may migrate to a dangerous or life threatening position. To reduce the likelihood of migration, a thrombus filter may include anchor members which penetrate the vessel walls.

5 The walls of the blood vessels are lined with a thin inner membrane which may be referred to as the intima or the endothelium. When this inner membrane is disrupted by a foreign object such as a thrombus filter the body responds in a process referred to as neointimal hyperplasia. As a result, the disrupted area of inner membrane is overgrown with a number of new cells. The anchor portions of the thrombus filter are encapsulated with new cell growth, referred to as endothelial
10 growth.

Due to neointimal hyperplasia, thrombus filters placed in the blood vessel of patient become affixed in the blood vessel walls within two weeks after being implanted. Because the portions of the filter contacting the blood vessel wall become fixed in this way, many prior art filters cannot be removed percutaneously after being
15 in place for more than two weeks.

Summary of the Invention

The present invention relates to a thrombus filter configured for placement within a blood vessel lumen defined by a blood vessel wall. The present invention
20 also relates to methods and devices for selectively reshaping the thrombus filter so that the lumen of the blood vessel is substantially unobstructed. One embodiment of a thrombus filter in accordance with the present invention includes a generally cylindrical anchoring portion and a generally conical filtering portion terminating at

an apex. The filtering portion includes a plurality of elongate strands arranged in an overlapping pattern to create a plurality of cells. The cells of the filtering portion allow blood to flow through the filtering portion of the thrombus filter with little resistance. The cells also enable the filtering portion to trap, or capture blood clots
5 traveling through the blood vessel lumen. The generally conical shape of the filtering portion urges captured blood clots toward the center of the blood flow. The flow of blood around the captured blood clots allows the body's natural lysing process to dissolve the clots.

The anchoring portion of the thrombus filter includes a plurality of elongated
10 strands arranged to create anchoring cells. The anchoring portion of the thrombus filter is adapted to expand radially in size so that it conforms to the walls of the blood vessel. In a presently preferred embodiment, the anchoring portion exerts a radial force on the walls of the blood vessel. The radial force exerted by the anchoring portion of the thrombus filter reduces the likelihood that the thrombus filter will
15 migrate within the lumen of the blood vessel.

In one embodiment of a thrombus filter in accordance with the present invention, a retaining means is disposed at the apex of the filter portion. The retaining means may include a coupling member fixed to its distal end. In this embodiment of the thrombus filter, the strands of the filter portion are biased to expand outward and
20 conform to the shape of the lumen of the blood vessel. The retaining means is adapted to retain the distal ends of the filter strands and maintain the generally conical shape of the filtering portion.

A catheter in accordance with the present invention may be used to remove the retaining means from the thrombus filter. When the retaining means is removed, the filtering portion of the thrombus filter converts from a generally conical shape to a generally cylindrical shape. When the filtering portion assumes a cylindrical shape, the strands are disposed proximate the blood vessels walls leaving the lumen substantially unobstructed.

A catheter in accordance with one embodiment of the present invention includes a lumen, a distal end, and a proximal end. An elongate member is disposed in the lumen of the catheter. The elongate member includes a distal end, a proximal end and coupling member disposed proximate the distal end. The coupling member of the elongate member of the catheter is adapted to couple with the coupling member of the retaining means. The proximal end of the elongate member protrudes beyond the proximal end of the catheter. Both the catheter and the elongate member extend outside the body of the patient.

To remove the retaining means from the thrombus filter, the distal end of the catheter is first positioned over the apex of the thrombus filter. The coupling member of the elongate member is then coupled with the coupling member of the retaining means. The retaining means may then be urged off of the thrombus filter. In a presently preferred embodiment, a pulling force is used to urge the retaining means away from the thrombus filter. Also in a presently preferred embodiment, this pulling force is created by pulling on the proximal end of the elongate member.

An additional embodiment of a thrombus filter in accordance with the present invention has also been envisioned. This thrombus filter includes a generally

cylindrical anchoring portion, and a generally conical filtering portion terminating at an apex. The filtering portion includes a plurality of filtering strands which converge at an apex to create a plurality of cells. In this embodiment of a thrombus filter, the filtering strands may be selectively deformed to convert the filtering portion from a generally conical shape to a generally cylindrical shape. When the filtering strands are selectively deformed to a cylindrical shape, they are disposed proximate the walls of the blood vessel leaving the vessel lumen substantially unobstructed.

A catheter in accordance with the present invention may be used to deform the strands of the filtering section of the thrombus filter. One embodiment of this catheter includes a distal end, and an expanding means disposed proximate the distal end. In a presently preferred embodiment, the catheter is a balloon catheter and the expanding means is a balloon. The catheter is urged forward within the vasculature of the patient until the expanding means is proximate the thrombosis filter. Specifically, the expansion means is positioned so that it is disposed within the filtering portion of the thrombus filter. The expansion means is then expanded. The expansion of the expansion means deforms the strands of the filter portion of the thrombus filter to a generally cylindrical shape. After the strands are deformed, they will be disposed proximate the walls of the blood vessel, leaving the blood vessel lumen substantially unobstructed.

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Brief Description of the Drawings

Figure 1 is a plan view of a thrombus filter disposed in the lumen of a blood vessel;

Figure 2 is an axial plan view of the thrombus filter of Figure 1;

Figure 3 is an enlarged plan view of a portion of the thrombus filter of Figure 1;

Figure 4 is an enlarged plan view of a portion of the thrombus filter of Figure 1;

Figure 5 is a plan view of an alternate embodiment of a thrombus filter in accordance with the present invention;

Figure 6 is an axial plan view of the thrombus filter of Figure 5;

Figure 7 is a plan view of the thrombus filter of Figure 5 in a configuration which leaves the lumen of the blood vessel substantially unobstructed;

Figure 8 is an axial plan view of a thrombus filter of Figure 7;

Figure 9 is a plan view of an alternate embodiment of a thrombus filter in accordance with the present invention;

Figure 10 is a plan view of the thrombus filter of Figure 9 with the filter portion configured so that the lumen of the blood vessel is substantially unobstructed;

Figure 11 is a plan view of an alternate embodiment of a thrombus filter in accordance with the present invention;

Figure 12 is an axial plan view of the thrombus filter of Figure 11.

20

Detailed Description of the Invention

The following detailed description should be read with reference to the drawings, in which like elements in different drawings are numbered identically. The

drawings which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention.

Examples of constructions, materials, dimensions, and manufacturing processes are provided for selected elements. All other elements employ that which
5 is known to those of skill in the field of the invention. Those skilled in the art will recognize that many of the examples provided have suitable alternatives which may be utilized.

Reference is now made to the drawings, in which like numbers refer to like elements throughout. Figure 1 is a plan view of a thrombus filter 20 disposed in a
10 lumen 100 defined by walls 102 of a blood vessel 104. Thrombus filter 20 includes a generally cylindrical anchoring portion 28, and a generally conical filtering portion 30 terminating at an apex 32.

Filtering portion 30 includes a plurality of elongated strands 40 including a plurality of bends 42. Strands 40 of filtering portion 30 are arranged in an
15 overlapping pattern to create a plurality of cells 44. Cells 44 are best shown in Figure 2.

Figure 2 is an axial plan view of the thrombus filter 20 of Figure 1. As described above, filtering portion 30 of thrombus filter 20 includes a plurality of cells 44. Cells 44 allow blood to flow through filtering portion 30 with little resistance.
20 Cells 44 also enable filtering portion 30 to trap, or capture blood clots traveling through blood vessel 104. The generally conical shape of filtering portion 30 urges captured blood clots toward the center of the blood flow. The flow of blood around the captured blood clots allows the body's natural lysing process to dissolve the clots.

Referring again to Figure 1, it may be appreciated that strands 40 extend beyond filtering portion 30 into anchoring portion 28. In the embodiment of Figure 1, strands 40 are arranged to create anchoring cells 46. Anchoring portion 28 of thrombus filter 20 is adapted to expand in size so that it conforms to walls 102 of blood vessel 104. Anchoring portion 28 is adapted to exert a radial force on walls 102 of blood vessel 104. The radial force exerted by anchoring portion 28 on walls 102 of blood vessel 104 reduces the likelihood that thrombus filter 20 will migrate within lumen 100 of blood vessel 104.

As seen in Figure 1, strands 40 are joined together at joined portions 50. Figure 3 is an enlarged plan view of joined portion 50. In the embodiment of Figure 3, joined portion 50 is created by twisting two strands 40 about each other. Other methods may be used to form joined portions 50 without departing from the spirit or scope of the present invention. Examples, of methods which may be suitable in some applications include mechanical fastening, soldering, brazing, resistance welding, and tungsten inert gas welding.

Also in the embodiment of Figure 1, cells 46 are joined together at joined portions 52. Figure 4 is an enlarged plan view of joined portion 52. In the embodiment of Figure 4, joined portion 52 is formed by passing two strands 40 and an anchor member 60 through a tubular member 48. In a presently preferred embodiment, tubular member 48 is comprised of metal tubing known in the art as hypotube. In this embodiment, anchor member 60 and one or more strands 40 pass through a lumen in a section of hypotubing. Also in a presently preferred embodiment, the hypotube section is fixed to the anchor member 60 and the one or

more strands 40. A number of methods may be used to fix the hypotube section to the anchor member and the one or more strands 40. For example, a mechanical connection may be formed by crimping the hypotube. By way of a second example, the hypotube section may be soldered to the anchor member 60 and strands 40. Other
5 processes which may be suitable in some applications include, brazing, resistance welding, and tungsten inert gas welding.

In a presently preferred embodiment, anchor members 60 include a sharp point capable of penetrating walls 102 of blood vessel 104. In this fashion, anchor members 60 reduce the likelihood that thrombus filter 20 will migrate upstream or
10 downstream in lumen 100 of blood vessel 104.

Walls 102 of blood vessel 104 are lined with a thin inner membrane which may be referred to as the intima or the endothelium. When this inner membrane is disrupted by a foreign object such as a thrombus filter the body responds in a process referred to as neointimal hyperplasia. As a result, the disrupted area of inner
15 membrane is overgrown with a number of new cells. The portions of a thrombus filter which are in contact with the intima will likely be encapsulated with new cell growth, referred to as endothelial growth.

In a presently preferred embodiment, strands 40 are generally circular in cross section. It should be understood that other cross-sectional shapes are possible without
20 deviating from the spirit or scope of the invention. For example, the cross-sectional shape of stands 40 could be circular, rectangular, square, triangular, oval, etc.

In a presently preferred embodiment, strands 40 are comprised of a nickel titanium alloy. Suitable nickel titanium materials are commercially available from

Memry Technologies (Brookfield, Connecticut), TiNi Alloy Company (San Leandro, California), and Shape Memory Applications (Sunnyvale, California). Strands 40 may be comprised of other metallic or non-metallic materials without departing from the spirit or scope of the present invention. Examples of metallic materials which may be suitable for some applications include stainless steel. Suitable, non-metallic materials suitable may be selected from the following list, which is not exhaustive: poly(L-lactide) (PLLA), poly(D,L-lactide) (PLA), polyglycolide (PGA), poly(L-lactide-co-D,L-lactide) (PLLA/PLA), poly(L-lactide-co-glycolide) (PLLA/PGA), poly(D, L-lactide-co-glycolide) (PLA/PGA), poly(glycolide-co-trimethylene carbonate) (PGA/PTMC), polyethylene oxide (PEO), polydioxanone (PDS), polycaprolactone (PCL), polyhydroxybutyrate (PHBT), poly(phosphazene), poly(D,L-lactide-co-caprolactone) (PLA/PCL), poly(glycolide-co-caprolactone) (PGA/PCL), polyanhydrides (PAN), poly(ortho esters), poly(phosphate ester), poly(amino acid), poly(hydroxy butyrate), polyacrylate, polyacrylamid, poly(hydroxyethyl methacrylate), polyurethane, polysiloxane and their copolymers.

In the embodiment of Figures 1-4, thrombus filter 20 includes a retaining means 80 disposed at apex 32 of filter portion 30. Retaining means 80 includes a coupling member 82 fixed to the distal end of retaining means 80. Strands 40 of filter portion 30 are biased to expand outward and conform to the shape of lumen 100 defined by walls 102 of blood vessel 104. Retaining means 80 is adapted to retain the distal ends of strands 40 and maintain the generally conical shape of filtering portion 30. In the embodiment of Figures 1-4, retaining means 80 is a collar which may be removed to selectively allow filter portion 30 to convert from a generally conical

shape to a generally cylindrical shape. When filtering portion 30 assumes a cylindrical shape, strands 40 are disposed proximate walls 102 of blood vessel 104, leaving lumen 100 substantially unobstructed.

Other embodiments of retaining means 80 have been envisioned. For example, retaining means 80 may be comprised of a twisted pattern formed by twisting the ends of strands 40 together.

Other embodiments of thrombus filter 20 have also been envisioned. Figure 5 is a plan view of an alternate embodiment of filter 20 in accordance with the present invention. Thrombus filter 20 of Figure 5 includes a generally cylindrical anchoring portion 28, and a generally conical filtering portion 30 terminating at an apex 32. Filtering portion 30 includes a plurality of filtering strands 140 which converge at apex 32 to create a plurality of cells 44. Cells 44 are best shown in Figure 6.

Figure 6 is an axial plan view of thrombus filter 20. As described above, filtering portion 30 of thrombus filter 20 includes a plurality of cells 44. Cells 44 allow blood to flow through filtering portion 30 with little resistance. Cells 44 also enable filtering portion 30 to trap, or capture blood clots traveling through the blood vessel. The generally conical shape of filtering portion 30 urges captured blood clots toward the center of the blood flow. The flow of blood around the captured blood clots allows the body's natural lysing process to dissolve the clots.

Referring again to Figure 5, anchoring portion 28 of thrombus filter 20 includes a plurality of anchoring strands 142 which are arranged to create anchoring cells 46. Anchoring portion 28 of thrombus filter 20 is adapted to expand in size so that it conforms to walls 102 of blood vessel 104. Anchoring portion 28 is adapted to

exert a radial force on walls 102 of blood vessel 104. The radial force exerted by anchoring portion 28 on walls 102 of blood vessel 104 reduces the likelihood that thrombus filter 20 will migrate within lumen 100 of blood vessel 104.

As seen in Figure 5, anchoring strands 142 are joined to filter strands 140 at joining portions 150. Also in the embodiment of Figure 5, each anchoring cell 46 is joined to one or more adjacent anchoring cells 46 by joining portions 152.

In a presently preferred embodiment, anchoring strands 142 are comprised of a nickel titanium alloy. Suitable nickel titanium materials are commercially available from Memry Technologies (Brookfield, Connecticut), TiNi Alloy Company (San Leandro, California), and Shape Memory Applications (Sunnyvale, California). Those with skill in the art will appreciate that anchoring strands 142 may be comprised of other materials without departing from the spirit or scope of the present invention.

In the embodiment of Figure 5, filtering strands 140 may be selectively deformed to convert filtering portion 30 from a generally conical shape to a generally cylindrical shape. Figure 7 is a plan view of thrombus filter 20 with a generally cylindrical filtering portion 30. Figure 8 is an axial plan view of view of thrombus filter 20 with filtering portion 30 selectively converted to a cylindrical shape. As shown in Figure 8, strands 40 are disposed proximate walls 102 of blood vessel 104, leaving blood vessel lumen 100 substantially unobstructed.

A method of selectively converting thrombus filter 20 from the shape illustrated in Figures 5 and 6 to the shape illustrated in Figures 7 and 8 may now be described. A method of selectively converting a thrombus filter in accordance with

the present invention would typically begin with the step of providing a catheter with an expanding means disposed at its distal end. In a presently preferred embodiment, the catheter is a balloon catheter and the expanding means is a balloon.

The catheter typically enters the patients vascular system at a point which is readily accessible to the physician. Once in the vascular system, the catheter is urged forward until the expanding means is proximate thrombus filter 20. Specifically, the expansion means is positioned so that it is disposed within filter portion 30. The expansion means is then expanded. The expansion of the expansion means deforms strands 140 of filter portion 30 to the generally cylindrical shape shown in Figures 7 and 8. As shown in Figures 7 and 8, strands 40 are disposed proximate walls 102 of blood vessel 104, leaving blood vessel lumen 100 substantially unobstructed.

Figure 9 is a plan view of an alternate embodiment of filter 20 in accordance with the present invention. Thrombus filter 20 of Figure 9 includes a generally cylindrical anchoring portion 28, and a generally conical filtering portion 30 terminating at an apex 32.

Filtering portion 30 includes a plurality of filtering strands 140 which converge at apex 32 to create a plurality of cells 44. Anchoring portion 28 of thrombus filter 20 includes a plurality of anchoring strands 142 which are arranged to create anchoring cells 46. Anchoring portion 28 of thrombus filter 20 is adapted to expand in size so that it conforms to walls 102 of blood vessel 104. Anchoring portion 28 is adapted to exert a radial force on walls 102 of blood vessel 104. The radial force exerted by anchoring portion 28 on walls 102 of blood vessel 104 reduces

the likelihood that thrombus filter 20 will migrate within lumen 100 of blood vessel 104.

As seen in Figure 9, anchoring strands 142 are joined to filter strands 140 at joining portions 144. Also in the embodiment of Figure 9, each anchoring cell 46 is
5 joined to one or more adjacent anchoring cells by joining portions 146.

In a presently preferred embodiment, anchoring strands 142 and filter strands 140 are comprised of a nickel titanium alloy. Suitable nickel titanium materials are commercially available from Memry Technologies (Brookfield, Connecticut), TiNi Alloy Company (San Leandro, California), and Shape Memory Applications
10 (Sunnyvale, California). As in the previous embodiment, anchoring strands 140 may be comprised of other materials without departing from the spirit or scope of the present invention.

In the embodiment of Figure 9, thrombus filter 20 includes a retaining means 80 disposed at apex 32 of filter portion 30. Filter strands 140 of filter portion 30 are
15 biased to expand outward and conform to the shape of lumen 100 defined by walls 102 of blood vessel 104. Retaining means 80 is adapted to retain the distal ends of filter strands 140 and maintain the generally conical shape of filtering portion 30. In the embodiment of Figure 9, retaining means 80 is a collar which may be removed to selectively allow filter portion 30 to convert from a generally conical shape to a
20 generally cylindrical shape. When filtering portion 30 assumes a cylindrical shape, filter strands 140 are disposed proximate walls 102 of blood vessel 104, leaving blood vessel lumen 100 substantially unobstructed. Retaining means 80 includes a coupling member 82 fixed to the distal end of retaining means 80.

A catheter 400 which may be used to selectively reshape thrombus filter 20 is also illustrated in Figure 9. Catheter 400 includes a lumen 402, a distal end 404, and a proximal end 406 (not shown). An elongate member 500 is disposed in lumen 402 of catheter 400. Elongate member 500 includes a distal end 504, a proximal end 506 (not shown), and a coupling member 502 disposed proximate distal end 504.

Coupling member 502 of elongate member 500 is adapted to couple with coupling member 82 of retaining means 80. Proximal end 506 (not shown) of elongate member 500 protrudes beyond proximal end 406 of catheter 400. Both catheter 400 and elongate member 500 extend outside the body of the patient. Catheter 400 further includes a retaining means 420. In the embodiment of Figure 9, the distal end of catheter 400 is disposed over apex 32 of thrombus filter 20 such that retaining means 80 is disposed in lumen 402 of catheter 400.

A method of converting a thrombus filter in accordance the instant embodiment the present invention may be described with reference to Figure 9. A catheter 400 with a lumen 402 and a distal end 404 is disposed in lumen 100 of blood vessel 104. Catheter 400 may enter the patients vascular system at a point which is readily accessible to the physician. Once in the vascular system, catheter 400 is urged forward until distal end 404 is proximate thrombus filter 20. For example, if thrombus filter 20 is located in the inferior vena cava of a patients vascular system, catheter 400 may enter the vascular system at the femoral vein. Alternately, if thrombus filter 20 is located in the superior vena cava of a patients vascular system, catheter 400 may enter the vascular system at the jugular vein. In either case, the

filter conversion procedure is minimally invasive, and does not require general anesthesia.

An elongated elongate member 500 including a distal end 504 and a proximal end 506 (not shown) is disposed in lumen 402 of catheter 400. In Figure 10, distal end 404 of elongate member 500 has been mated to coupling member 82 of retaining means 80. Proximal end 506 of elongated elongate member 500 protrudes beyond proximal end 406 of catheter 400. Both catheter 400 and elongate member 500 extend outside the body of the patient.

When distal end 104 of catheter 400 reaches a position proximate thrombus filter 20, distal end 104 is urged further forward so that retaining means 80 of thrombus filter 20 is pushed into lumen 402 of catheter 400. Coupling member 502 of elongated elongate member 500 is then coupled to coupling member 82 of retaining means 80. With elongated elongate member 500 affixed to coupling member 82 of retaining means 80, retaining means 80 may be readily separated from thrombus filter 20 by applying a pulling force to proximal end 506 of elongate member 500. This pulling force is transferred via elongate member 500 to retaining means 80. The pulling force applied to elongate member 500 of thrombus filter 20 pulls retaining means 80 off of the distal ends of strands 40. Once retaining means 80 has been removed, strands 40 are free to spring outward allowing filtering portion 30 to assume a generally cylindrical shape. Once retaining means 80 is inside lumen 402; catheter 400 may be withdrawn from blood vessel 104. Retaining means 420 assures that retaining means 80 does not exit lumen 402 of catheter 400 and become loose in blood vessel 104.

Figure 11 is a plan view of an alternate embodiment of filter 20 in accordance with the present invention. Thrombus filter 20 of Figure 11 includes a generally cylindrical anchoring portion 28, and a generally conical filtering portion 30 terminating at an apex 32.

5 Filtering portion 30 includes a plurality of filtering strands 140 which converge at apex 32 to create a plurality of cells 44. Anchoring portion 28 of thrombus filter 20 includes a plurality of anchoring strands 142 which are arranged to create anchoring cells 46. Anchoring portion 28 of thrombus filter 20 is adapted to expand in size so that it conforms to walls 102 of blood vessel 104. Anchoring
10 portion 28 is adapted to exert a radial force on walls 102 of blood vessel 104. The radial force exerted by anchoring portion 28 on walls 102 of blood vessel 104 reduces the likelihood that thrombus filter 20 will migrate within lumen 100 of blood vessel 104.

As seen in Figure 11, anchoring strands 142 are joined to filter strands 140 at
15 joining portions 144. In the embodiment of Figure 11, joining portions 144 are weld beads. A number of welding processes may be suitable for creating joining portions 144 of Figure 11. For example, tungsten inert gas (TIG) welding, resistance welding, and LASER welding may all be suitable in some applications.

In the embodiment of Figure 11, thrombus filter 20 includes a retaining means
20 80 disposed at apex 32 of filter portion 30. Filter strands 140 of filter portion 30 are biased to expand outward and conform to the shape of lumen 100 defined by walls 102 of blood vessel 104. Retaining means 80 is adapted to retain the distal ends of strands 40 and maintain the generally conical shape of filtering portion 30. In the

embodiment of Figure 11, retaining means 80 is a collar which may be removed to selectively allow filter portion 30 to convert from a generally conical shape to a generally cylindrical shape. When filtering portion 30 assumes a cylindrical shape, strands 40 are disposed proximate walls 102 of blood vessel 104, leaving blood vessel lumen 100 substantially unobstructed. Retaining means 80 includes a coupling element 182 proximate to the distal end of retaining means 80.

Figure 12 is an axial plan view of the thrombus filter 20 of Figure 11. As best seen in Figure 12, each filtering strand 140 is formed in generally helical, or spiraled shape. The diameter of the helix varies along the length of each filter strand 140 to form the generally conical shape of filter portion 30. As shown in Figure 12, cells 44 defined by filter strands 140 are generally spiraled in nature.

Numerous advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of parts without exceeding the scope of the invention. The inventions's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A thrombus filter for placement within a blood vessel lumen defined by a blood vessel wall comprising:
 - a wall engaging portion comprised of a plurality of wall engaging strands;
 - a filtering portion comprised of a plurality of filtering strands;
 - each filtering strand having a joined end and a free end;
 - the joined end of each filtering strand being fixed to the thrombus filter;
 - the free ends of the filtering strands converging at an apex of the thrombus filter; and
 - a means for retaining disposed about the free ends of the filtering strands;
2. The thrombus filter of claim 1, wherein the filtering strands include a plurality of bends.
3. The thrombus filter of claim 1, wherein the filtering strands are arranged to define a plurality of filtering cells.
4. The thrombus filter of claim 1, wherein the wall engaging portion is generally cylindrical in shape.
5. The thrombus filter of claim 1, wherein the wall engaging portion is biased to radially expand.

6. The thrombus filter of claim 1, wherein the filtering portion is biased to radially expand.

7. The thrombus filter of claim 1, wherein the filtering portion is retained in generally conical shape by the means for retaining.

8. The thrombus filter of claim 1, wherein the means for retaining is a collar.

9. The thrombus filter of claim 1, wherein the means for retaining includes a coupling member.

10. The thrombus filter of claim 9, wherein the coupling member is a hook.

11. The thrombus filter of claim 9, wherein the coupling member is a loop.

12. The thrombus filter of claim 9, wherein the coupling member is a shoulder.

13. A method of selectably re-shaping a thrombus filter disposed within a blood vessel lumen, defined by a blood vessel wall, the method comprising the steps of:

providing a thrombus filter having a wall engaging portion comprising a plurality of wall engaging strands and a filtering portion comprising a plurality of filtering strands;

each filtering strand having a joined end and a free end;

the joined end of each filtering strand being fixed to the thrombus filter;

the free ends of the filtering strands converging at an apex of the thrombus filter; and

a means for retaining disposed about the free ends of the filtering strands;

positioning an elongated force transferring member so that a distal end thereof is proximate the means for retaining of the thrombus filter;

coupling the elongated force transferring member to the means for retaining;

and

removing the means for retaining from the thrombus filter.

14. A thrombus filter for placement within a blood vessel lumen defined by a blood vessel wall comprising:

a wall engaging portion comprising a plurality of wall engaging strands;

a filtering portion comprising a plurality of filtering strands;

each filtering strand having a joined end and a free end;

the joined end of each filtering strand being fixed to the thrombus filter; and

the free ends of the filtering strands converging at an apex of the thrombus filter.

15. The thrombus filter of claim 14, wherein the filtering strands include a plurality of bends.

16. The thrombus filter of claim 14, wherein the filtering strands are arranged to define a plurality of filtering cells.

17. The thrombus filter of claim 14, wherein the wall engaging portion is generally cylindrical in shape.

18. The thrombus filter of claim 14, wherein the wall engaging portion is biased to radially expand.

19. The thrombus filter of claim 14, wherein the filtering portion is generally conical in shape.

20. A method of selectably re-shaping a thrombus filter disposed within a blood vessel lumen, defined by a blood vessel wall, the method comprising the steps of:

providing a thrombus filter having a wall engaging portion comprising a plurality of wall engaging strands and a filtering portion comprising a plurality of filtering strands;

each filtering strand having a joined end and a free end;

the joined end of each filtering strand being fixed to the thrombus filter;

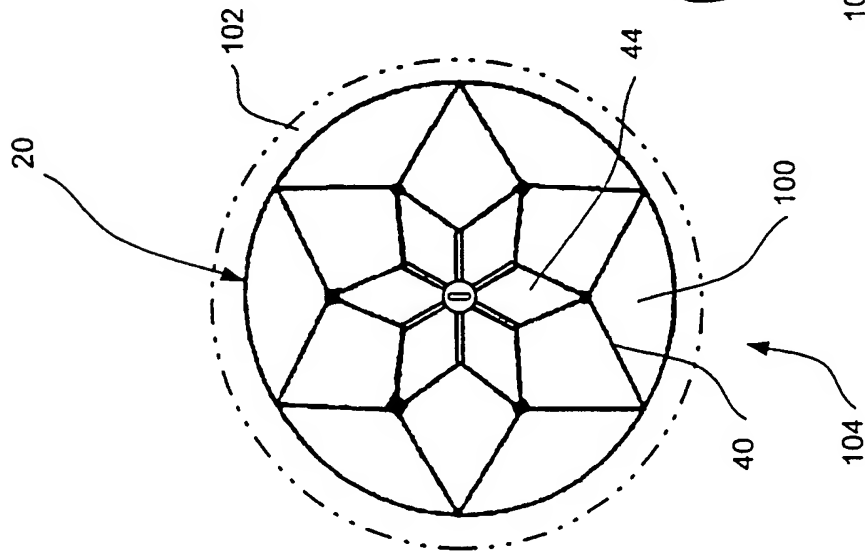
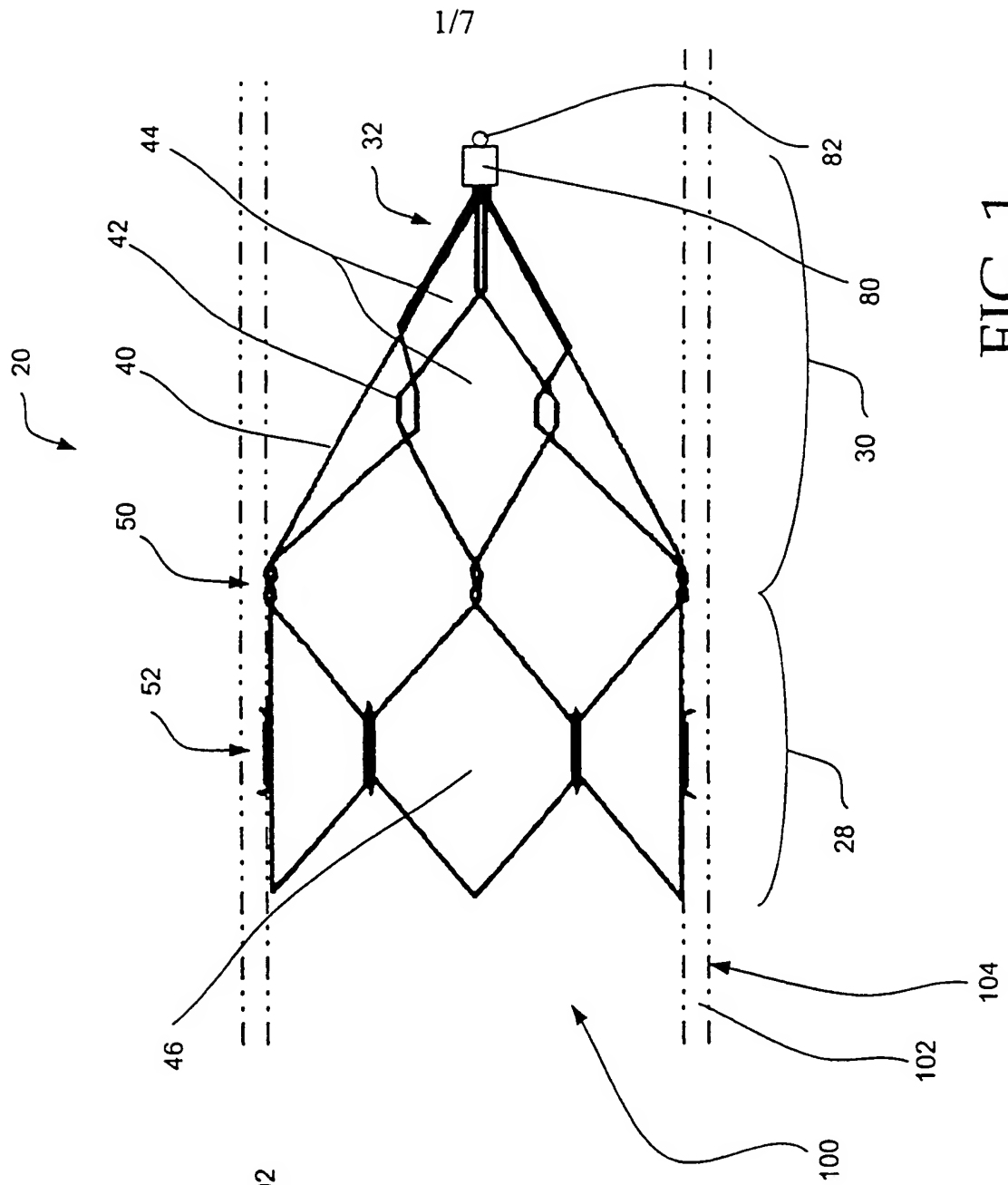
the free ends of the filtering strands converging at an apex of the thrombus filter;

providing an elongate catheter having a means for expansion disposed proximate a distal end thereof;

positioning the elongate catheter within the blood vessel lumen so that the distal end thereof is proximate the filtering portion of the thrombus filter;

expanding the means for expansion of the elongate catheter;

wherein the free ends of the filtering strands are urged toward the blood vessel walls.



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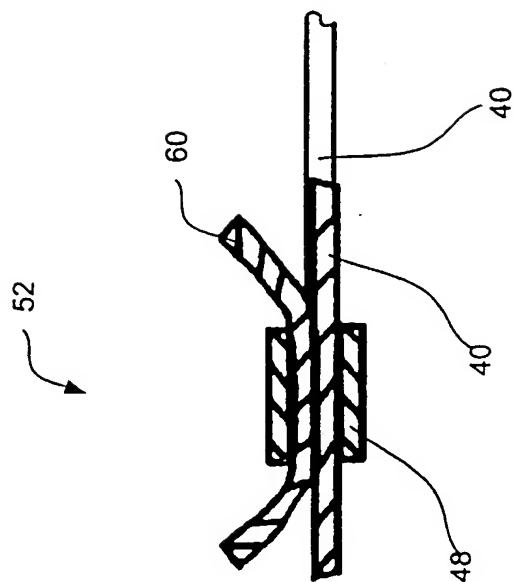


FIG. 3

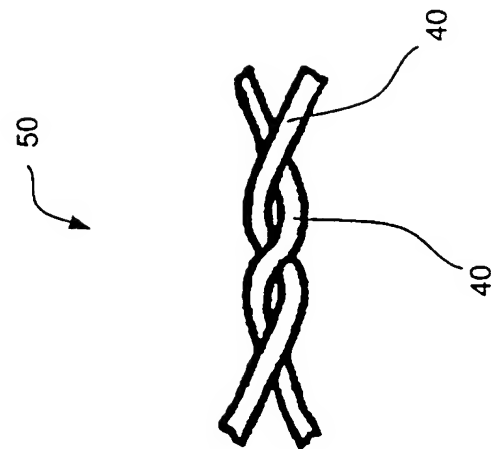


FIG. 4

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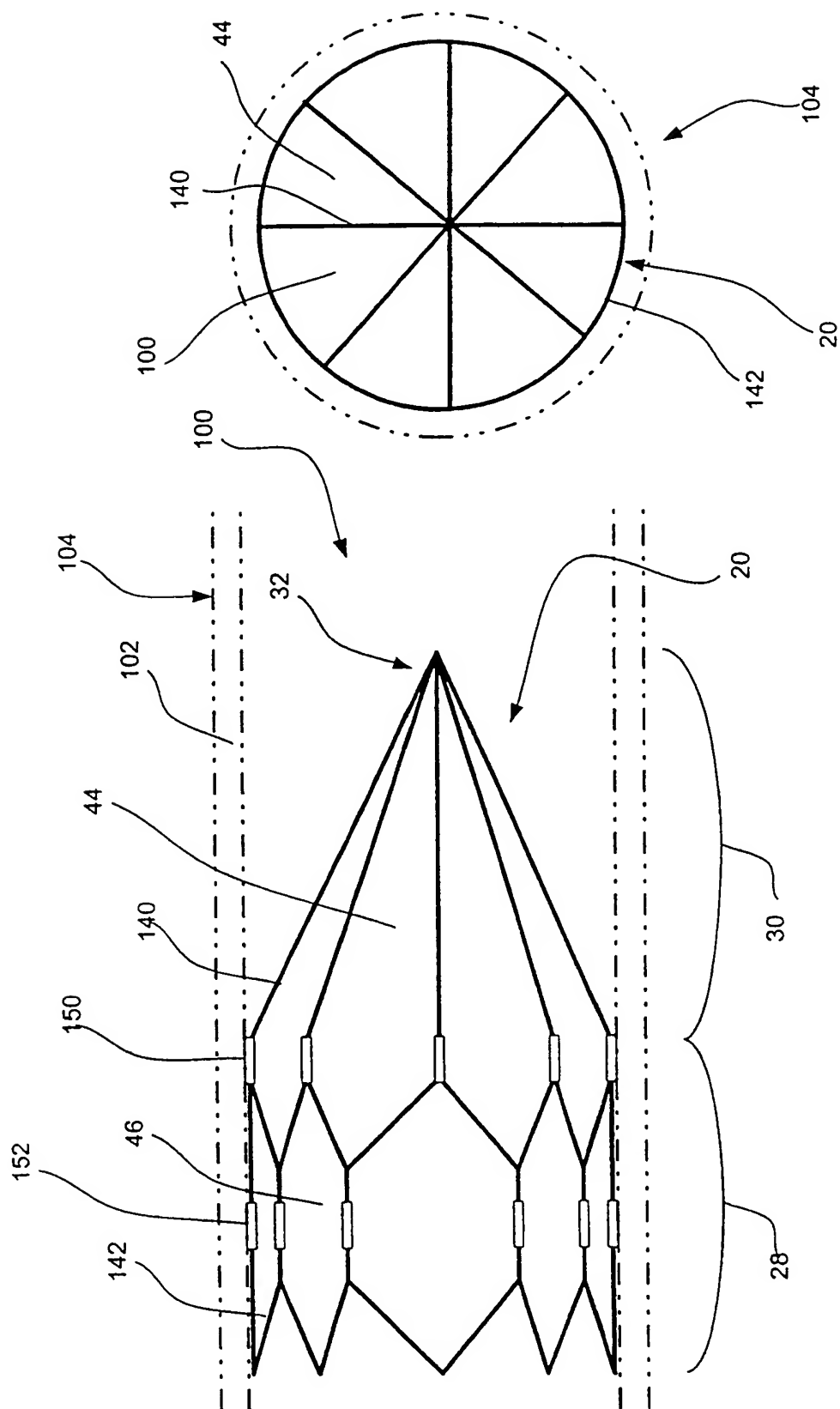
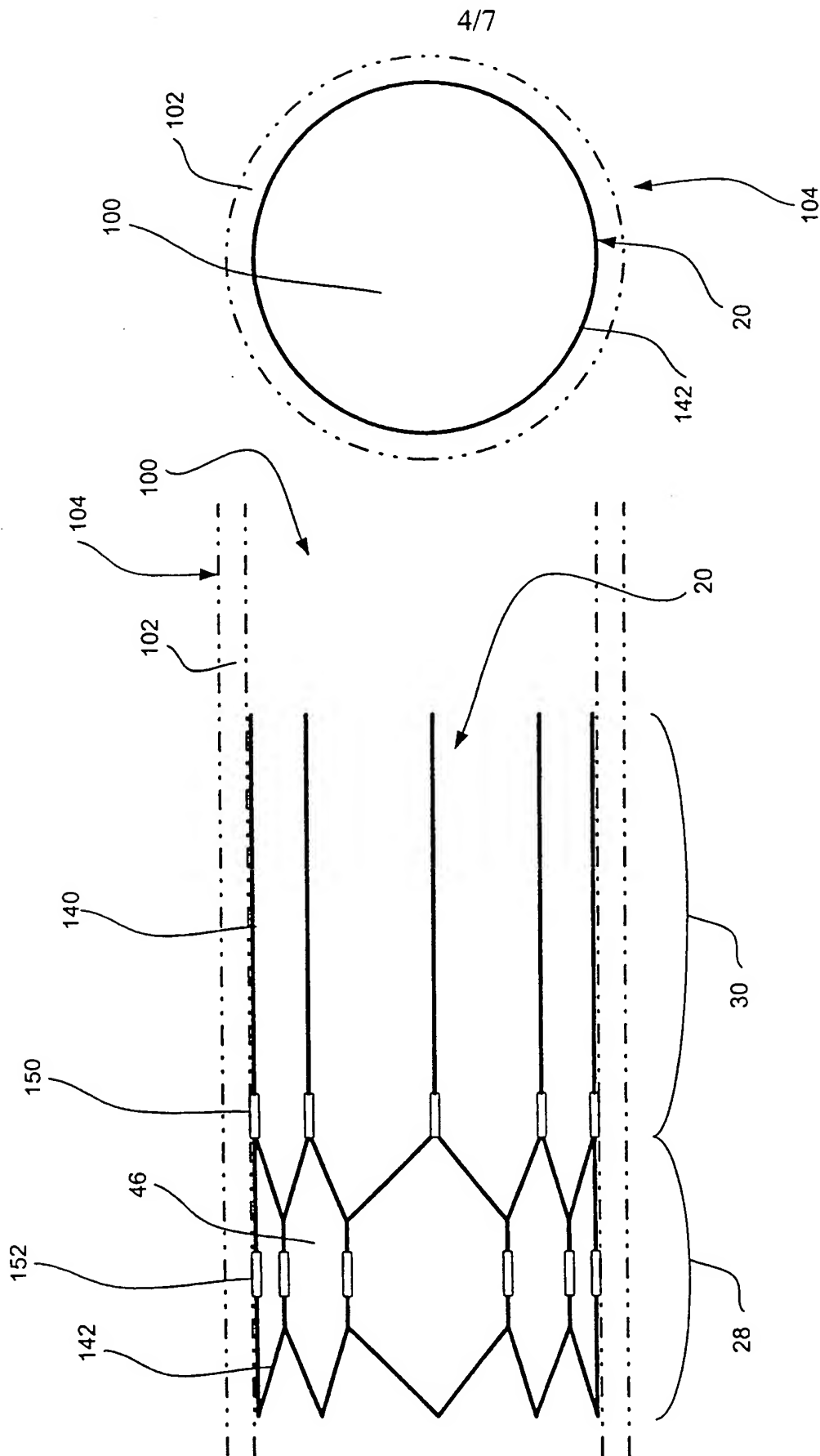


FIG. 5

FIG. 6



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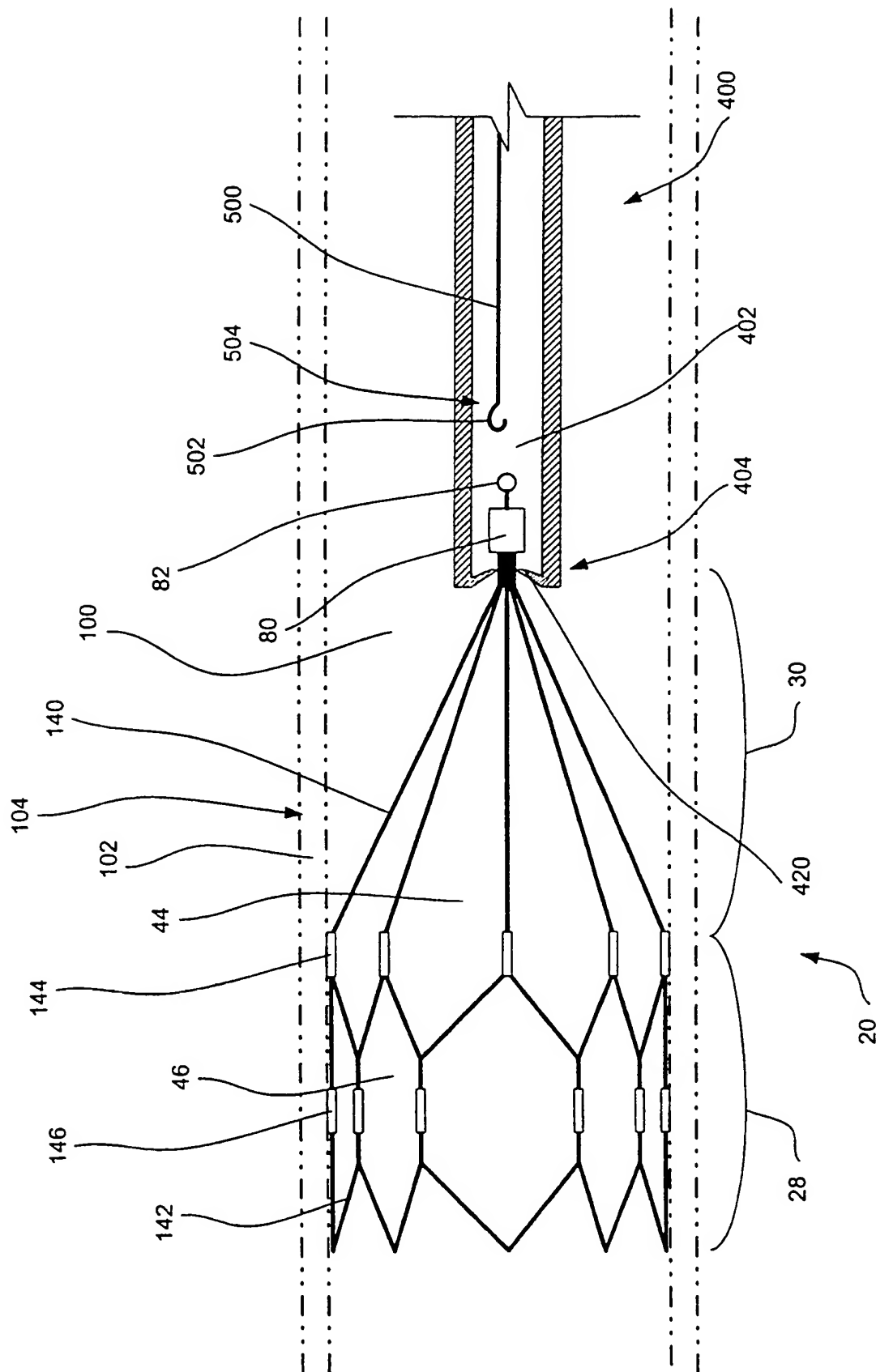


FIG. 9

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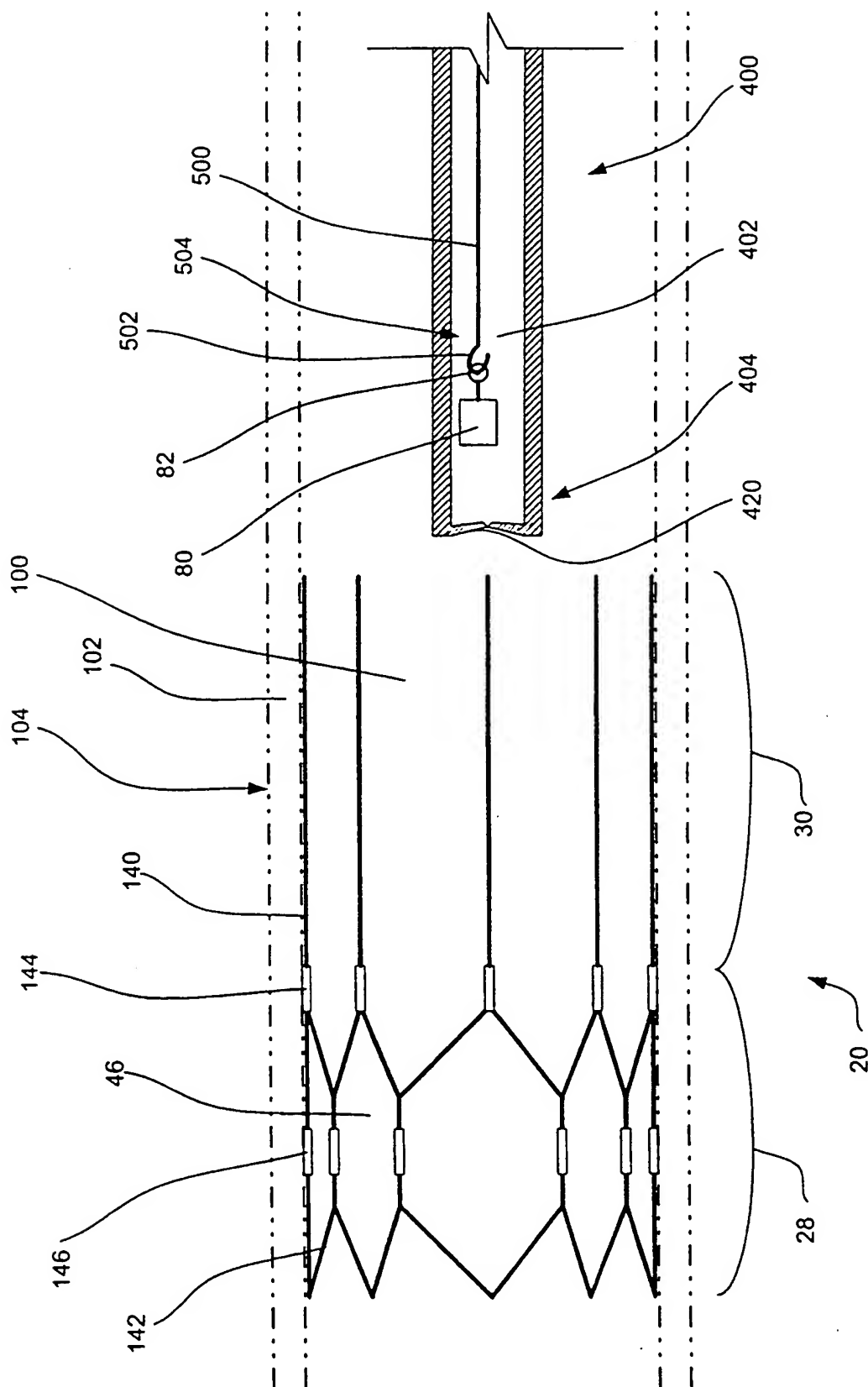


FIG. 10

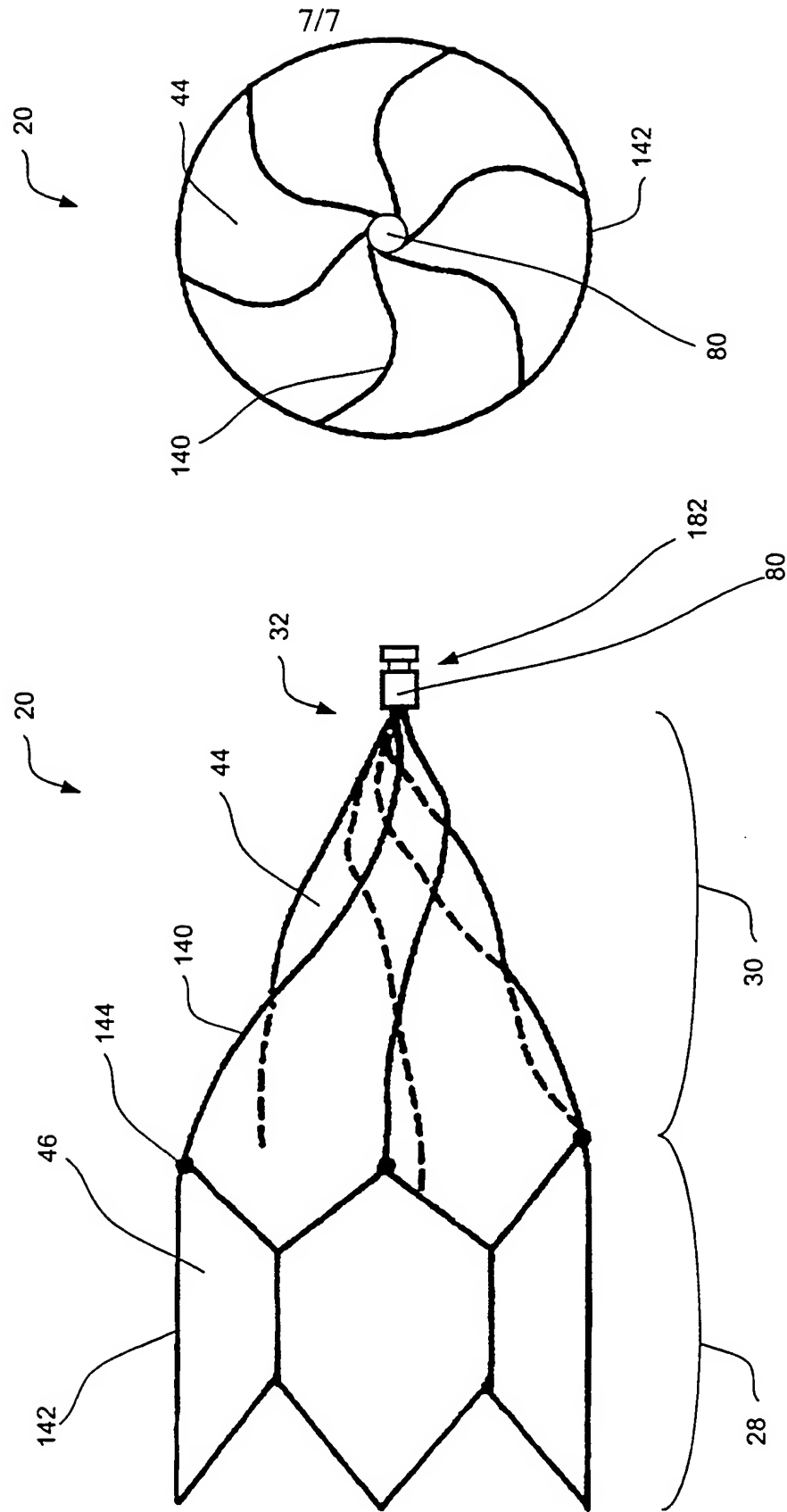


FIG. 11

FIG. 12

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(71) Applicant: **BOSTON SCIENTIFIC LIMITED** [IE/IE];
The Corporate Centre, Bush Hill, Bay Street, St Michael,
Barbados, West Indies (IE).

(74) Agents: **SEAGER, Glenn, M.** et al.; Crompton, Seager
& Tufts, LLC, 331 Second Avenue South, Suite 895, Min-
neapolis, MN 55401 (US).

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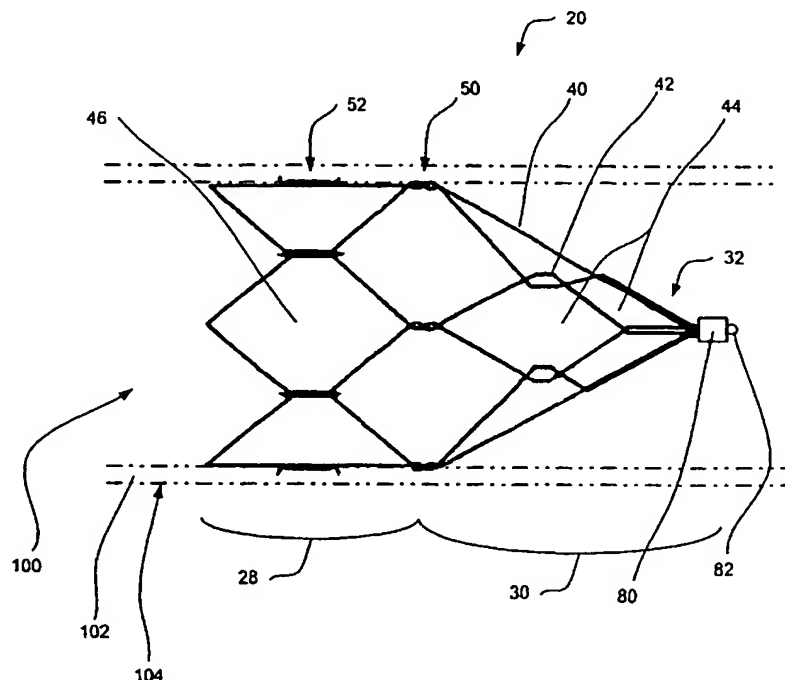
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(54) Title: INTRAVASCULAR FILTERING DEVICES AND METHODS



(57) Abstract: A thrombus filter configured for placement within a blood vessel lumen defined by a blood vessel wall. Methods and devices for selectively reshaping the thrombus filter so that the lumen of the blood vessel is substantially unobstructed. The thrombus filter includes a generally cylindrical anchoring portion, and a generally conical filtering portion terminating at an apex.



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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 013 093 A (SUON NAROUN ET AL) 11 January 2000 (2000-01-11) claims; figures ----	1-5,7,8, 14-19
P,X	WO 00 66031 A (CONNELL PAUL T O) 9 November 2000 (2000-11-09) the whole document ----	1,2, 4-10,14, 15,17-19
A	WO 98 02112 A (FOUERE ALAIN) 22 January 1998 (1998-01-22) page 3, line 23 -page 4, line 15; figures -----	1,3-6, 14,16-19

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European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6013093 A	11-01-2000	US 6214025 B EP 0794744 A JP 10509623 T	10-04-2001 17-09-1997 22-09-1998
WO 0066031 A	09-11-2000	US 6267776 B AU 4816400 A	31-07-2001 17-11-2000
WO 9802112 A	22-01-1998	AU 6617396 A	09-02-1998